

510(k) SUMMARY

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This summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is: K122809

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Product Names:

Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dipcard
Advin Multi-Drug Screen Test Cup

Common Name:

Immunochromatographic test for the qualitative detection of multi-drugs and/or their metabolites in human urine.

Device Classification:

The Advin Multi-Drug Screen Test Cassette, Dipcard and Cup are similar to other FDA-cleared devices for the qualitative detection of following drugs in urine specimens:

| Drug Test | Calibrator | Cutoff |
|-----------------------|---|-----------|
| Amphetamine (AMP) | d-Amphetamine | 500 ng/mL |
| Barbiturates (BAR) | Secobarbital | 300 ng/mL |
| Benzodiazepines (BZO) | Oxazepam | 300 ng/mL |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL |
| Cocaine (COC) | Benzoylcegonine | 150 ng/mL |
| EDDP | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 ng/mL |

| Drug Test | Calibrator | Cutoff |
|--------------------------------|--------------------------------|-------------|
| Ecstasy (MDMA) | Methylenedioxymethamphetamine | 500 ng/mL |
| Methamphetamine (MET) | d-Methamphetamine | 500 ng/mL |
| Methadone (MTD) | Methadone | 300 ng/mL |
| Morphine (MOR300) | Morphine | 300 ng/mL |
| Opiates (OPI) | Morphine | 2,000 ng/mL |
| Oxycodone (OXY) | Oxycodone | 100 ng/mL |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL |
| Propoxyphene (PPX) | Propoxyphene | 300 ng/mL |
| Tricyclic-antidepressant (TCA) | Nortriptyline | 1,000 ng/mL |
| Marijuana (THC) | 11-nor- Δ^9 -THC-9-COOH | 50 ng/mL |

These tests are used to provide only preliminary test results. The test systems have been classified as Class II devices with moderate complexity.

Classification Name:

Amphetamine Test System
Methamphetamine Test System
Barbiturates Test System
Benzodiazepine Test system
Antidepressant test system
Opiate Test System
Cannabinoids Test System
Cocaine and cocaine metabolite Test System
Methadone Test System
Tricyclic Antidepressants Test System
Methadone Test System
Propoxyphene test system

Intended Use:

The Advin Multi-Drug Screen Test is a one-step immunoassay for the qualitative detection of multiple drugs of abuse and/or their metabolites in human urine at the following cutoff levels:

| Drug Test | Calibrator | Cutoff |
|---------------------|--------------------------------|----------|
| Amphetamine (AMP) | d-Amphetamine | 500 |
| Barbiturates (BAR) | Secobarbital | 300 |
| Benzodiazepines | Oxazepam | 300 |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL |
| Cocaine (COC) | Benzoylcegnine | 150 |
| EDDP | 2-ethylidene-1,5-dimethyl-3,3- | 300 |
| Ecstasy (MDMA) | Methylenedioxymethamphetamine | 500 |

| | | |
|--------------------------|--------------------------------|-------------|
| Methamphetamine | d-Methamphetamine | 500 |
| Methadone (MTD) | Methadone | 300 |
| Morphine (MOR300) | Morphine | 300 |
| Opiates (OPI) | Morphine | 2,000 |
| Oxycodone (OXY) | Oxycodone | 100 |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL |
| Propoxyphene (PPX) | Propoxyphene | 300 |
| Tricyclic-antidepressant | Nortriptynine | 1,000 ng/mL |
| Marijuana (THC) | 11-nor- Δ^9 -THC-9-COOH | 50 ng/mL |

The Advin Multi-Drug Screen Test consists of three formats: a Cassette, a Dipcard and a Cup format, which may be configured in any combination of the drugs analytes listed in the above table.

Advin Multi-Drug Screen Test is used to obtain a visual, qualitative, preliminary test result for prescription use in point of care sites, laboratory settings and is also intended for workplace and over-the-counter use. The Propoxyphene test strip is not intended for over-the-counter use.

This test does not distinguish between drugs of abuse and certain medications. It will yield preliminary positive results when prescription drugs TCA, Barbiturates, Benzodiazepine, Methadone, Buprenorphine and Opiates drugs are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for these prescription drugs in urine.

This assay provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry/Mass (LC/MS/MS) and High Performance Liquid Chromatography (HPLC) are the preferred confirmatory methods.

Clinical considerations and professional judgment should always be applied to interpret any drug of abuse test result, particularly in evaluating a preliminary positive test result.

Description:

The Advin Multi-Drug Screen Test is a lateral flow immunochromatographic competitive binding assay and is intended for prescription use, CLIA Waived use and OTC use. It is used as *in vitro* diagnostics to visually and qualitatively detect some of the most common drugs of abuse and/or their metabolites in human urine specimens. The test is based on the principle of competitive binding antigen-antibody immunochemistry. It utilizes anti-drug antibody to selectively detect elevated levels of multi-drugs and/or their metabolites in urine at a specified cutoff for each drug. These visual read tests are performed without the use of an instrument.

A drug-Positive urine specimen **will not** generate a colored-line in the designated test region, while a drug-Negative urine specimen or a urine specimen containing drug(s) at the concentration below the cut-off level **will** generate a colored-line in the test region. To serve as a procedural control, a

colored-line will always appear at the control region, indicating that proper volume of urine specimen has been added and membrane wicking has occurred.

Some of the Advin Multi-Drug Screen Test will be sold with either one or two adulteration test strips for the detection of adulterants added to the urine specimen. Each Adulteration strip consists of one to three reagent pads which consist of tests for oxidant, specific gravity, pH, glutaraldehyde, creatinine and nitrite.

Predicate Devices and 510(k) Numbers:

Innovacon Spectrum II Test Card and Test Card with Integrated Test Cup (K061718)

Comparison to a Predicate Device:

The ADVIN Multi-Drug Screen Test (Cassette, Dipcard and Cup) have following similarities compared to the above predicate devices:

- All tests are assays intended for the qualitative detection of drugs in urine samples.
- All tests are intended as a screening method that provides a preliminary qualitative analytical test result.
- All tests are immunochromatographic, lateral flow, competitive binding assays for the rapid detection of drug and drug metabolites with a visual, qualitative end result.
- All tests utilize the same basic immunoassay principles that rely on antigen/ antibody interaction to indicate a positive or a negative result.
- All tests have the same cutoff for each of drugs with the exception of Amphetamine test.

| Feature | Advin Multi-Drug Screen Test | Predicate devices |
|--------------------------------------|--|---|
| Indication of use | A rapid chromatographic immunoassay for the qualitative detection of multiple drugs/metabolites in human urine. | A rapid chromatographic immunoassay for the qualitative and simultaneous detection of multiple drugs and metabolites in human urine. |
| Cutoff Concentrations (ng/mL) | Amphetamine 500 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1,000, EDDP 300 | Amphetamine 1000 or 300 Barbiturates 300 Benzodiazepines 300 Buprenorphine 10 Cocaine 150 or 300 Methadone 300 MDMA 500 THC 50 Methamphetamine 500 or 1,000 morphine 300, or opiates 2,000 Oxycodone 100 Phencyclidine 25 Propoxyphene 300 Tricyclic antidepressants 1,000 EDDP 300 |

| | | |
|---------------------------|---|---|
| Intended use | Prescription use, CLIA-waived laboratory and Over-the-Counter use | Professionals and point of care sites |
| Intended specimen | Urine | Urine |
| Endpoint | Colored Lines | Same |
| Materials provided | Test Devices (Cassette, Dipcard, Cup) Package Insert | Test Devices (Test Card, Cup) Package Insert |
| Methodology | Membrane Particle Assay | Same |
| Test Time | 5 minutes | Same |
| Format | Immunochemical Antigen/Antibody Immunoassay | Same |

Safety and Effectiveness Data:

Accuracy

The accuracy of Advin Multi-Drug Screen Test was evaluated in comparison to GC/MS analysis data. Forty drug-free urine specimens collected from presumed non-user volunteers were tested with Advin Multi-Drug Screen Test. Of these 40 negative specimens tested, all were correctly identified as negative. 10% of these negative specimens were confirmed with GC/MS as drug negative urine specimens. At least 40 drug positive urine specimens for each drug test were obtained from reference labs throughout the United States. The drug concentration in each of the positive specimen was confirmed with GC/MS and LC/MS (for TCA analysis). Summary of accuracy results on Advin Multi-Drug Screen Test Cassette, Dipcard and Cup are shown in tables below:

A. Summary of Accuracy Results on Advin Multi-Drug Screen Test Cassette:

| Drug Test | Test Result | Compared to GC/MS Analysis Data | | | | | | |
|-----------|-------------|---------------------------------|------------------------|------------------|-----------------|-----------------------|-----------|-------------|
| | | Drug-free | -50% C/O to < -25% C/O | -25 C/O % to C/O | C/O to +25% C/O | >+25% C/O to +50% C/O | >+50% C/O | % agreement |
| AMP 500 | Neg | 40 | 3 | 0 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 2 | 2 | 45 | 100% |
| BAR 300 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.2% |
| | Pos | 0 | 0 | 2 | 5 | 2 | 36 | 100% |
| BUP 10 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 8 | 0 | 32 | 100% |
| BZO 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 1 | 6 | 34 | 100% |
| COC 150 | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 4 | 1 | 53 | 100% |
| EDDP 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 5 | 2 | 33 | 100% |
| MDMA 500 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 5 | 1 | 34 | 100% |
| MET 500 | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 1 | 3 | 51 | 100% |
| MOR 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 4 | 0 | 53 | 100% |
| MTD 300 | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 4 | 0 | 37 | 100% |
| OPI | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |

| | | | | | | | | |
|-------|-----|----|---|---|---|---|----|-------|
| 2,000 | Pos | 0 | 0 | 2 | 4 | 3 | 40 | 100% |
| OXY | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| 100 | Pos | 0 | 0 | 3 | 7 | 1 | 33 | 100% |
| PCP | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7 |
| 25 | Pos | 0 | 0 | 1 | 3 | 8 | 33 | 100% |
| PPX | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 95.3% |
| 300 | Pos | 0 | 0 | 2 | 5 | 2 | 33 | 100% |
| TCA | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| 1,000 | Pos | 0 | 0 | 2 | 5 | 7 | 28 | 100% |
| THC | Neg | 40 | 1 | 2 | 0 | 0 | 0 | 97.7% |
| 50 | Pos | 0 | 0 | 1 | 4 | 7 | 44 | 100% |

B. Summary of Accuracy Results on Advin Multi-Drug Screen Test Dipcard:

| Drug Test with Cutoff (ng/mL) | Test Result | Compared to GC/MS Analysis Data | | | | | | |
|-------------------------------|-------------|---------------------------------|------------------------|------------------|-----------|-----------------------|-----------|-----------|
| | | Drug-free | -50% C/O to < -25% C/O | -25 C/O % to C/O | Drug-free | >+25% C/O to +50% C/O | >+50% C/O | Drug-free |
| AMP | Neg | 40 | 3 | 0 | 0 | 0 | 0 | 97.7% |
| 500 | Pos | 0 | 0 | 1 | 2 | 2 | 45 | 100% |
| BAR | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.2% |
| 300 | Pos | 0 | 0 | 2 | 5 | 2 | 36 | 100% |
| BUP | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| 10 | Pos | 0 | 0 | 2 | 8 | 0 | 32 | 100% |
| BZO | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| 300 | Pos | 0 | 0 | 3 | 1 | 6 | 34 | 100% |
| COC | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7% |
| 150 | Pos | 0 | 0 | 1 | 4 | 1 | 53 | 100% |
| EDDP | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| 300 | Pos | 0 | 0 | 3 | 5 | 2 | 33 | 100% |
| MDMA | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| 500 | Pos | 0 | 0 | 2 | 5 | 1 | 34 | 100% |
| MET | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| 500 | Pos | 0 | 0 | 3 | 1 | 3 | 51 | 100% |
| MOR | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| 300 | Pos | 0 | 0 | 3 | 4 | 0 | 53 | 100% |
| MTD | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| 300 | Pos | 0 | 0 | 2 | 4 | 0 | 37 | 100% |
| OPI | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| 2,000 | Pos | 0 | 0 | 2 | 4 | 3 | 40 | 100% |
| OXY | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| 100 | Pos | 0 | 0 | 3 | 7 | 1 | 33 | 100% |
| PCP | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7 |
| 25 | Pos | 0 | 0 | 1 | 3 | 8 | 33 | 100% |
| PPX | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 95.3% |
| 300 | Pos | 0 | 0 | 2 | 5 | 2 | 33 | 100% |
| TCA | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| 1,000 | Pos | 0 | 0 | 2 | 5 | 7 | 28 | 100% |
| THC | Neg | 40 | 1 | 2 | 0 | 0 | 0 | 97.7% |
| 50 | Pos | 0 | 0 | 1 | 4 | 7 | 44 | 100% |

C. Summary of Accuracy Results on Advin Multi-Drug Screen Test Cup:

| Drug Test with Cutoff (ng/mL) | Test Result | Compared to GC/MS Analysis Data | | | | | | |
|-------------------------------|-------------|---------------------------------|------------------------|-----------------|-----------------|-----------------------|-----------|-------------|
| | | Drug-free | -50% C/O to < -25% C/O | -25% C/O to C/O | C/O to +25% C/O | >+25% C/O to +50% C/O | >+50% C/O | % agreement |
| AMP 500 | Neg | 40 | 3 | 0 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 2 | 2 | 45 | 100% |
| BAR 300 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.2% |
| | Pos | 0 | 0 | 2 | 5 | 2 | 36 | 100% |
| BUP 10 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 8 | 0 | 32 | 100% |
| BZO 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 1 | 6 | 34 | 100% |
| COC 150 | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 4 | 1 | 53 | 100% |
| EDDP 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 5 | 2 | 33 | 100% |
| MDMA 500 | Neg | 40 | 1 | 1 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 5 | 1 | 34 | 100% |
| MET 500 | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 1 | 3 | 51 | 100% |
| MOR 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 4 | 0 | 53 | 100% |
| MTD 300 | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 4 | 0 | 37 | 100% |
| OPI 2,000 | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 2 | 4 | 3 | 40 | 100% |
| OXY 100 | Neg | 40 | 1 | 0 | 0 | 0 | 0 | 93.2% |
| | Pos | 0 | 0 | 3 | 7 | 1 | 33 | 100% |
| PCP 25 | Neg | 40 | 0 | 3 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 3 | 8 | 33 | 100% |
| PPX 300 | Neg | 40 | 0 | 1 | 0 | 0 | 0 | 95.3% |
| | Pos | 0 | 0 | 2 | 5 | 2 | 33 | 100% |
| TCA 1,000 | Neg | 40 | 0 | 2 | 0 | 0 | 0 | 95.5% |
| | Pos | 0 | 0 | 2 | 5 | 7 | 28 | 100% |
| THC 50 | Neg | 40 | 1 | 2 | 0 | 0 | 0 | 97.7% |
| | Pos | 0 | 0 | 1 | 4 | 7 | 44 | 100% |

Analytical Specificity

The following compounds are detected positive in urine by the Advin Multi- Drug Screen Test Cassette, Dip card, and Cup; the concentration of each cross-reactive compound which produced a positive result is in ng/mL and the percentage of the cross-reactivity relative to the calibrator is in parenthesis:

| Compounds | Concentration (%) | Compounds | Concentration (%) |
|---------------|-------------------|---------------|-------------------|
| AMP | | | |
| D-Amphetamine | 500 (100%) | L-amphetamine | 50,000 (1%) |
| MDA | 8,000 (6.5%) | Phentermine | 45,000 (1.1%) |
| BAR | | | |
| Secobarbital | 300 (100%) | Amobarbital | 2,500 (12%) |
| Aprobarbital | 500 (60%) | Butobarbital | 100 (300%) |

| | | | |
|--------------------|----------------|-------------------------|----------------|
| Butalbital | 300 (100%) | Cyclopentobarbital | 500 (60%) |
| Phenobarbital | 300 (100%) | Phentobarbital | 250 (120%) |
| BUP | | | |
| Buprenorphine | 10 (100%) | | |
| BZO | | | |
| Oxazepam | 300 (100%) | Alpha-hydroxyalprazolam | 1,900 (15.8%) |
| Alprazolam | 200 (150%) | Bromazepam | 1,000 (30%) |
| Clobazam | 200 (150%) | Clorazepam | 750 (40%) |
| Desalkylflurazepam | 1,200 (25%) | Diazepam | 1,000 (30%) |
| Flunitrazepam | 250 (120%) | Lorazepam | 3,900 (7.7%) |
| Nitrazepam | 250 (120%) | Lorazepam-glucuronide | 5,000 (6%) |
| Nordiazepam | 390 (76.9%) | Nordiazepoxide | 400(75%) |
| Temazepam | 150 (200%) | Norchlordiazepapoxide | 500 (60%) |
| Triazolam | 2,500 (12%) | | |
| COC | | | |
| Benzoyllecgonine | 150 (100%) | Cocaine | 5,000 (3%) |
| Cocaethylene | 50,000 (0.3%) | Ecgonine | 50,000 (0.3%) |
| EDDP | | | |
| EDDP | 300 (100%) | | |
| MET | | | |
| d-Methamphetamine | 500 (100%) | 1R,2S(-) -Ephedrine | 100,000 (0.5%) |
| d-Amphetamine | 50,000 (1%) | L-Amphetamine | 50,000 (1%) |
| MDEA | 30,000 (1.7%) | Mephentermine | 75,000 (0.7%) |
| MDMA | 3,500 (14.3%) | | |
| MDMA | | | |
| (+/-) – MDMA | 500 (100%) | (+/-)-MDA | 3,900 (12.8%) |
| (+/-)- MDEA | 500 (100%) | | |
| MTD | | | |
| Methadone | 300 (100%) | | |
| MOR | | | |
| Morphine | 300 (100%) | Codeine | 100 (300%) |
| Ethylmorphine | 100 (300%) | Heroin | 8,000 (37.5%) |
| Hydrocodone | 1,250 (24%) | Hydromorphone | 2,500 (12%) |
| Levophenol | 50,000 (0.6%) | Morphine 3-glucuronide | 400 (75%) |
| Norcodeine | 6,000 (1.9%) | Oxycodone | 75,000 (0.4%) |
| Thebaine | 90,000 (0.3%) | | |
| PCP | | | |
| Phencyclidine | 25 (100%) | 4-hydroxy-PCP | 1,500 (1.7%) |
| OPI | | | |
| Morphine | 2,000 (100%) | Oxycodone | 70,000 (2.9%) |
| Codeine | 1,800 (111.1%) | Morphine-3-glucuronide | 2,600 (76.9%) |
| Ethylmorphine | 1500 (133.3%) | Hydrocodone | 5,000 (40%) |
| Hydromorphone | 5,000 (40%) | Thebaine | 95,000 (2.1%) |
| Heroin | 11,000 (18.2%) | | |
| OXY | | | |
| Oxycodone | 100 (100%) | Hydromorphone | 25,000 (0.4%) |
| Hydrocodone | 5,000 (2%) | Oxymorphone | 12,500 (0.8) |
| Ethymorphine | 50,000 (0.2%) | Codeine | 50,000 (0.2%) |

PPX

| | | | |
|--------------|------------|-----------------|------------|
| Propoxyphene | 300 (100%) | Nor-propoxyphen | 300 (100%) |
|--------------|------------|-----------------|------------|

TCA

| | | | |
|---------------|--------------|---------------|--------------|
| Nortriptyline | 1,000 (100%) | Amitriptyline | 4,000 (25%) |
| Clomipramine | 2,000 (50%) | Doxepine | 1,000 (100%) |
| Desipramine | 500 (200%) | Imipramine | 1,000 (100%) |
| Promethazine | 1,000 (100%) | Trimipramine | 5,000 (20%) |

THC

| | | | |
|--------------------------------|---------------|----------------------------------|---------------|
| 11-nor- Δ^9 -THC-9-COOH | 50 (100%) | (+/-)11-hydroxy- Δ^9 -THC | 5,000 (1%) |
| (-)- Δ^8 -THC | 20,000 (0.3%) | (-)- Δ^9 -THC | 20,000 (0.3%) |

Precision:

The precision of Advin Multi-Drug Screen Test was evaluated at 3 Physician's Office Laboratory sites and 100 lay persons. Data obtained from these sites indicate that correct test results can be obtained when urine specimen with drug concentrations at +/-50% cutoff levels are tested with Advin Multi-Drug Test Cassette, Dipcard, and Cup.

Lay-Users Study

A total of over one hundred male and female persons age 18 or older participated in the lay person user study with Advin Multi -Drug Screen Test following product package insert. The drug-free urine specimens together with spiked urine specimens with different drug concentrations at +/- 50% cutoff and +/- 25% cutoff were tested by the participants. Each level of the drug solutions was randomly tested with at least 20 replicates.

The lay person user study results indicates that the agreement between the testing results from lay person and GC/MS analysis results is from over 99% for the concentrations at +/- 50% cutoff levels and 65% to 86% for the concentrations near the cutoff levels and. The statistic analysis indicates that a lay person can follow the product package insert and perform Advin Multi-Drug Screen Test Cassette, Dip Card and Cup similar to professionals at POL sites with reasonable accuracy.

A Summary of the lay person user study results are listed in the tables below:

Analysis of Discordant Results with Advin Multi-drug Screen Cassette by Lay Person vs. GC/MS Analysis

| Drug test cutoff (ng/mL) | Number of tests (discordant results/total results) | Result of Advin Multi-drug Test Cassette | GC/MS or LCMS (ng/mL) |
|--------------------------|--|--|-----------------------|
| AMP 500 | 12 /136 | Positive | 366 |
| | 7/86 | Negative | 555 |
| BAR 300 | 5/65 | Positive | 227 |
| | 4/44 | Negative | 394 |
| BUP 10 | 6/66 | Positive | 6.9 |
| | 6/44 | Negative | 11.3 |

| | | | |
|----------|------|----------|------|
| BZO 300 | 6/65 | Positive | 209 |
| | 4/41 | Negative | 374 |
| COC 150 | 6/68 | Positive | 113 |
| | 4/42 | Negative | 186 |
| EDDP | 5/66 | Positive | 212 |
| | 6/42 | Negative | 406 |
| MET 500 | 6/62 | Positive | 394 |
| | 5/44 | Negative | 646 |
| MDMA 500 | 6/62 | Positive | 368 |
| | 6/46 | Negative | 624 |
| MTD 300 | 7/64 | Positive | 218 |
| | 3/44 | Negative | 412 |
| MOR 300 | 5/62 | Positive | 255 |
| | 6/47 | Negative | 318 |
| OPI 2000 | 5/64 | Positive | 1465 |
| | 4/44 | Negative | 2135 |
| OXY | 6/70 | Positive | 67 |
| | 3/42 | Negative | 112 |
| PCP 25 | 7/68 | Positive | 17.2 |
| | 3/41 | Negative | 35.2 |
| TCA 1000 | 6/68 | Positive | 784 |
| | 4/42 | Negative | 1210 |
| THC 50 | 6/62 | Positive | 34.1 |
| | 5/48 | Negative | 57.1 |

Analysis of Discordant Result with Advin Multi-drug Screen Dipcard by Lay Person vs. GC/MS Analysis

| Drug test cutoff (ng/mL) | Number of tests (discordant results/total results) | Result of Advin Multi-drug Test Dipcard | GC/MS or LCMS (ng/mL) |
|--------------------------|--|---|-----------------------|
| AMP 500 | 12/126 | Positive | 366 |
| | 7/86 | Negative | 555 |
| BAR 300 | 5/66 | Positive | 227 |
| | 6/40 | Negative | 394 |
| BUP 10 | 4/63 | Positive | 6.9 |
| | 4/42 | Negative | 11.3 |
| BZO 300 | 4/63 | Positive | 209 |
| | 4/42 | Negative | 374 |
| COC 150 | 5/64 | Positive | 113 |
| | 4/45 | Negative | 186 |
| EDDP 300 | 5/62 | Positive | 212 |
| | 6/43 | Negative | 406 |
| MET 500 | 6/65 | Positive | 394 |
| | 4/40 | Negative | 646 |
| MDMA 500 | 5/63 | Positive | 368 |
| | 6/41 | Negative | 624 |
| MTD 300 | 6/63 | Positive | 218 |
| | 5/42 | Negative | 412 |
| MOR 300 | 5/65 | Positive | 255 |

| | | | |
|----------|------|----------|------|
| | 4/44 | Negative | 318 |
| OPI 2000 | 5/63 | Positive | 1465 |
| | 5/41 | Negative | 2125 |
| OXY 100 | 5/62 | Positive | 67 |
| | 4/41 | Negative | 112 |
| PCP 25 | 5/64 | Positive | 17.2 |
| | 4/42 | Negative | 35.2 |
| TCA 1000 | 5/62 | Positive | 784 |
| | 4/43 | Negative | 1210 |
| THC 50 | 6/65 | Positive | 34.1 |
| | 4/44 | Negative | 57.1 |

**Analysis of Discordant Result with Advin Multi-drug Screen Cup by Lay Person vs.
GC/MS Analysis**

| Drug test cutoff (ng/mL) | Number of tests (discordant results/total results) | Result of Advin Multi-drug Test Cup | GC/MS or LCMS (ng/mL) |
|-----------------------------|--|--|--------------------------|
| AMP 500 | 23/256 | Positive | 366 |
| | 22/176 | Negative | 555 |
| BAR 300 | 5/193 | Positive | 227 |
| | 6/42 | Negative | 394 |
| BUP 10 | 4/191 | Positive | 6.9 |
| | 6/44 | Negative | 11.3 |
| BZO 300 | 6/196 | Positive | 209 |
| | 6/41 | Negative | 374 |
| COC 150 | 6/194 | Positive | 113 |
| | 5/43 | Negative | 186 |
| EDDP 300 | 6/194 | Positive | 212 |
| | 5/43 | Negative | 406 |
| MET 500 | 6/195 | Positive | 394 |
| | 5/42 | Negative | 646 |
| MDMA 500 | 5/191 | Positive | 368 |
| | 6/43 | Negative | 624 |
| MTD 300 | 5/193 | Positive | 218 |
| | 6/44 | Negative | 412 |
| MOR 300 | 6/127 | Positive | 255 |
| | 5/42 | Negative | 381 |
| OPI 2000 | 5/129 | Positive | 1465 |
| | 4/41 | Negative | 2125 |
| OXY 100 | 7/194 | Positive | 67 |
| | 5/43 | Negative | 112 |
| PCP 25 | 6/194 | Positive | 17.2 |
| | 4/41 | Negative | 35.2 |
| TCA 1000 | 5/192 | Positive | 784 |
| | 6/43 | Negative | 1210 |
| THC 50 | 6/195 | Positive | 34.1 |
| | 5/42 | Negative | 57.1 |

Conclusion:

From data collected in the accuracy and precision studies, it was demonstrated that Advin Multi-Drug Screen Test is safe and effective to use when compared to predicate devices already marketed in the United States.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 17, 2013

Advin Biotech
C/O Edward Tung
6861 Nancy Ridge Dr., Suite #D
SAN DIEGO CA 92121

Re: K122809

Trade/Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dipcard
Advin Multi-Drug Screen Test Cup

Regulation Number: 21 CFR 862.3100

Regulation Name: Amphetamine test system

Regulatory Class: II

Product Code: DKZ, DJC, DIS, JXM, DJG, LDJ, DIO, DJR, LFG, JXN, LCM

Dated: June 03, 2013

Received: June 06, 2013

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucml15809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Courtney H. Lias, Ph.D.

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k122809

Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dip Card
Advin Multi-Drug Screen Test Cup

Indications for Use:

The Advin Multi-Drug Screen Test is a one-step immunoassay for the qualitative detection of multiple drugs of abuse and/or their metabolites in human urine at the following cutoff levels:

| Drug Test | Calibrator | Cutoff Level |
|--------------------------------|---|--------------|
| Amphetamine (AMP) | d-Amphetamine | 500 ng/mL |
| Barbiturates (BAR) | Secobarbital | 300 ng/mL |
| Benzodiazepines (BZO) | Oxazepam | 300 ng/mL |
| Buprenorphine (BUP) | Buprenorphine | 10 ng/mL |
| Cocaine (COC) | Benzoylcegnine | 150 ng/mL |
| EDDP | 2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine | 300 ng/mL |
| Ecstasy (MDMA) | Methylenedioxyamphetamine | 500 ng/mL |
| Methamphetamine (MET) | d-Methamphetamine | 500 ng/mL |
| Methadone (MTD) | Methadone | 300 ng/mL |
| Morphine (MOR300) | Morphine | 300 ng/mL |
| Opiates (OPI) | Morphine | 2,000 ng/mL |
| Oxycodone (OXY) | Oxycodone | 100 ng/mL |
| Phencyclidine (PCP) | Phencyclidine | 25 ng/mL |
| Propoxyphene (PPX) | Propoxyphene | 300 ng/mL |
| Tricyclic-antidepressant (TCA) | Nortriptynine | 1,000 ng/mL |
| Marijuana (THC) | 11-nor- Δ^9 -THC-9-COOH | 50 ng/mL |

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler-S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health
510(k) k122809

Indications for Use

510(k) Number (if known): k122809

Device Name: Advin Multi-Drug Screen Test Cassette
Advin Multi-Drug Screen Test Dip Card
Advin Multi-Drug Screen Test Cup

Indications for Use:

The Advin Multi-Drug Screen Test consists of three formats: a Cassette, a Dip Card and a Cup, which may be configured in any combination of the drug analytes listed in the above table.

Advin Multi-Drug Screen Test is used to obtain a visual, qualitative, preliminary test result for prescription use in point of care sites, laboratory settings and is also intended for workplace and over-the-counter use. The Propoxyphene test strip is not intended for over-the-counter use.

The Advin Multi-Drug Screen Test will yield preliminary positive results when prescription drugs TCA, Barbiturates and Benzodiazepine, Methadone, Buprenorphine and Opiates are ingested, even at or above therapeutic doses. There are no uniformly recognized drug levels for TCA, Barbiturates and Benzodiazepine in urine.

The Advin Multi-Drug Screen Test provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical test result. Gas chromatography/mass spectrometry (GC/MS), Liquid Chromatography / Mass Spectrometry/Mass (LC/MS/MS) and High Performance Liquid Chromatography-(HPLC)-are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly in the evaluation of a preliminary positive test result.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use X
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Ruth A. Chesler -S

Division Sign-Off

Office of In Vitro Diagnostics and Radiological Health

510(k) k122809